

REMARKS

Claims 1-15 are pending in the application. Claims 1 -13 have been amended to correct certain informalities. No new matter is added by these amendments.

New claims 14 and 15 have been added, but do not include new matter. Support for claims 14 and 15 are found at least in the specification as filed at paragraph 45 of United States Patent Application Publication No. 2004/0126332.

I. Rejection Under 35 U.S.C. § 103(a) Over Mannara in View of Thombre

The Examiner has rejected claims 1-13 under 35 U.S.C. § 103(a) based upon the combination of United States Patent No. 4,003,971 of Mannara ("Mannara"), taken in view of United States Patent Application Publication No. 2002/0034542 of Thombre *et al.* ("Thombre").

In support of the Mannara-Thombre rejection, the Examiner reasons that Mannara teaches "speckles" for incorporation into "clear dentifrices," which allegedly provide an attractive appearance. The Examiner further argues that the speckles contain many of the ingredients recited in claim 2-13. However, the Examiner concedes that Mannara lacks a teaching of a speckle containing starch.

An effort the remedy this deficiency is made by the application of Thombre, which, according to the Examiner, teaches rapidly disintegrating and fast-dissolving solid dosage forms that include polymers. According to the Examiner, these polymers include manmade and natural polymers such as HPMC, PVA, PVP, acacia, or high amylose starch. The Examiner concedes, however, that the polymeric dosage forms of Thombre are not included in a dentifrice.

The Examiner concludes:

It would have been obvious to one of ordinary skill in the art to have used the polymers in the secondary reference to make the speckles in the primary reference motivated by the desire to be able to deliver therapeutic agents incorporated into the speckles rapidly upon brushing, to ensure the speckles dissolve when in the mouth, to be able to shape the speckles to the desired shape or thinness and to use materials commonly found in toothpaste.

Office Action at 4.

The applicants respectfully traverse the rejection.

Mannara teaches a method of preparing particles or "speckles" which can subsequently be incorporated into a paste or powder dentifrice. *E.g.*, col. 1 at lines 5-9.

Mannara teaches that the speckles are globular or spherical in shape having an effective diameter of about 0.5 to 1 mm. See, *e.g.*, col. 2 at lines 38-40; Examples 1, 3, and 4 (green spherical particles); Example 2 (yellow spherical particles). Moreover, Mannara provides no specific teaching of "speckles" made of cellulose polymers and starch.

Finally, as the Examiner herself has pointed out, Mannara does not teach incorporation of flakes containing aesthetic or functional components.

Thombre discloses non-friable, rapidly disintegrating, fast-dissolving solid dosage forms for use in systemic delivery of pharmaceuticals through the oral, vaginal, buccal, or rectal routes, *e.g.*, paragraph 44. The dosage form is made up of pharmaceutically acceptable polymers including high amylose starches and HPMC. No teaching of the incorporation of the dosage form into any other substance is provided.

In order to demonstrate a *prima facie* case of obviousness based on a combination of references, the Examiner must establish that (i) the combined art teaches or suggests each element of the invention as claimed, (ii) a person of skill in the art would have been motivated to make the combination proposed; and (iii) a person of skill in the art would have had a reasonable expectations that the combination would have been successful. In the present situation, the Examiner has failed to meet this burden for the reasons discussed below.

The Mannara-Thombre Combination Lacks At Least Three Elements of the Invention

The Mannara-Thombre combination does not teach or suggest the invention as claimed. Mannara teaches only the presence of spherical or globular speckles in toothpaste. The speckles are not flakes, they are spherical. Further, Mannara provides no teaching of flakes having a water hydratable matrix, the matrix comprised of a homogenous mixture of water soluble hydroxyalkyl cellulose polymer and a starch. Thus, the disclosure of Mannara is lacking at least three elements of the invention as claimed.

The deficiencies of Mannara are not remedied by combining it with the disclosure of Thombre. Thombre teaches a dosage form containing various permutations of polymers. These dosages forms are disclosure for use to systemically administer pharmaceuticals via the oral, vaginal, buccal, or rectal routes and are taught

as taking the shape of tablets or suppositories. Thombre does not teach a dosage form that is a flake having a water hydratable matrix, the matrix comprised of a homogenous mixture of water soluble hydroxyalkyl cellulose polymer and a starch. Thus, the disclosure of Thombre is lacking at least three elements of the invention as claimed.

Because each of Mannara and Thombre lack at least the same three elements of the invention as claimed, the combination of Mannara and Thombre does not provided a combination that teaches or suggests each element of the invention as claimed.

Motivation to Make the Mannara-Thombre Combination Is Not Present

Moreover, a person of skill in the art would have had no motivation to make the combination suggested by the Examiner to arrive at the invention as claimed.

Mannara is concerned with devising a method of production of speckles such that the resultant speckles are of uniform shape and size. Thombre, in contrast, is focused on the preparation of dosage forms for systemic delivery of pharmaceuticals via the oral, buccal, vaginal, and rectal rout in the form of tablets or suppositories. No teaching in Thombre identifies or suggests that they should be incorporated into any sort of carrier or vehicles, such as a dentifrice. Moreover, such forms are known in the art to be large in scale such that one could not comfortably place more than one in the oral cavity and brush. Accordingly, there is no motivation in either the references or the art that would have provoked a person of skill in the art at the time the invention was made to make such combination.

The Examiner suggests that the person of skill would have been motivated to incorporate the high amylose starch of Thombre into the speckles of Mannara to facilitate the dissolution of the speckles upon brushing. However, the references do not support this interpretation. Mannara is silent on the any difficulty experienced in the dissolution of the speckles. Thombre clearly identifies that the high amylose starch is a desirable ingredient for its dosage forms because of the starch's high degree of resilience and lack of friability. Thombre does not teach that use of the high amylose starch shall increase dissolution of the dosage form.

No Reasonable Expectation of Success Is Present

At the time the invention was made, a person of skill in the art would not have had a reasonable expectation that the combination of Mannara and Thombre would have been successful. As discussed above, any dentifrice resulting from the

replacement of the speckles with the dosage form would result in an unwieldy and uncomfortable-to use toothpaste. Additionally, one of skill in the art upon review of Thombre may have concluded that use of the dosages forms and/or materials of Thombre in a dentifrice would be infeasible because such forms would dissolve prior to use by the consumers.

In view of the foregoing, it is respectfully requested that the Examiner reconsider and withdraw the rejection.

II. Rejection Under 35 U.S.C. § 103(a) Over Mannara in View of Graff-Anderson

The Examiner has rejected claims 1-13 under 35 U.S.C. § 103(a) based upon the combination of Mannara taken in view of United States Patent No. 5,869,029 of Graff-Anderson *et al.* ("Graff-Anderson").

In support of the Mannara - Graff-Anderson rejection, the Examiner applies Mannara as in (i) but asserts that its deficiencies are remedied by the disclosure of Graff-Anderson. According to the Examiner, Graff-Anderson teaches that cream, opaque and transparent and translucent toothpastes are produced. These toothpastes contain polymer binders or thickeners, such as cellulose ether, guar, starches, and chitins to prevent lump formations in the toothpaste products.

The Examiner concedes, however, that Graff-Anderson does not teach use of these binders in a flake form that contains a functional or aesthetic agent.

The Examiner concludes:

It would have been obvious to one of ordinary skill in the art to have used polysaccharides such as cellulose ethers and starch of the secondary reference and incorporated them into the clear dentifrice of the primary reference motivated by the desire to use materials commonly found in toothpaste that can form agglomerates such as flakes that are stable in the presence of other components found within the toothpaste compositions.

Office Action at 5.

The applicants respectfully traverse the rejection.

Mannara is summarized above. Graff-Anderson discloses compositions that contain particles of partially-agglomerated water-soluble or water-swellaable polymers, including toothpastes. Graff-Anderson asserts that such compositions addressed the need in the industry for methods of producing lump-free compositions, using the water-soluble binders which are time-effective and logistically simple. Col. 1, lines 36-

42. The agglomerated particles of Graff-Anderson are noted for their rapid dissolution once incorporated into the end formulation, *e.g.*, toothpaste.

The agglomerated compositions of this invention hydrate or dissolve in water or water-containing solvents substantially faster without formation of polymer lumps than do the corresponding untreated water-soluble or water-swellaable polymers.

Col. 3, line 66 to col. 4, line 4; *see also*, col. 4, line 12-20 (comparison of prior art slow dissolution rate to agglomerated rapid rate, "lumpy" versus smooth end composition).

Graff-Anderson teaches that the agglomerated particles are incorporated into the toothpaste by stirring it with a humectant, until the particulate agglomerates are fully dissolved or swollen. *See*, col. 4, lines 63-66. As the Examiner argues, Graff-Anderson is silent on use of polymers in the form of flakes in a dentifrice composition. **The Mannara-Graff-Anderson Combination Lacks At Least Three Elements of the Invention**

As discussed above, the Mannara reference lacks at least three elements of the invention as claimed. Specifically, Mannara provides no teaching of flakes having a water hydratable matrix, the matrix comprised of a homogenous mixture of water soluble hydroxyalkyl cellulose polymer and a starch.

Nor does Graff-Anderson disclose these three elements. Graff-Anderson teaches a method of preparing a dentifrice that incorporates partially-agglomerated water-soluble or water swellaable polymers into the dentifrice to provide a smooth, continuous composition that lacks "polymer lumps." It is clear from the disclosure of Graff-Anderson the polymers are thoroughly incorporated into the composition and are not, therefore, present as discrete particulates, such as the "speckles" called for in Mannara or the "flakes" of the present invention.

Because each of Mannara and Graff-Anderson lack at least the same three elements of the invention as claimed, the combination of Mannara and Graff-Anderson does not provide a combination that teaches or suggests each element of the invention as claimed.

Motivation to Make the Mannara-Graff-Anderson Combination Is Not Present

A person of skill in the art would have had no motivation to make the combination suggested by the Examiner to arrive at the invention as claimed.

Mannara is concerned with devising a method of production of speckles such that the

resultant speckles are of uniform shape and size and provide a discernable and pleasing aesthetic device in the dentifrice. Graff-Anderson is concerned with the preparation of a lump-free dentifrice - i.e., one that presumably does not have speckles. The agglomerated particulate components of Graff-Anderson are dissolved into the balance of the dentifrice. They do not remain as particulates. Because of the starkly different foci of the two technologies, a person of skill in the art would not have been motivated to make the combination proposed by the Examiner.

No Reasonable Expectation of Success Is Present

A person of skill would not have had a reasonable expectation that the combination proposed by the Examiner would be successful. As discussed above, Graff-Anderson seeks to incorporate the polymer materials into the dentifrice such the resulting composition is sooth and lump free. Mannara seeks to prepare speckles that will provide aesthetic effect while serving as "lumps" in the dentifrice. For at least these reasons, the technologies of the references are incompatible. A person of skill in the art would not have had a reasonable expectation that the combination as proposed by the example would be successful.

In view of the foregoing, it is requested that the Examiner reconsider and withdraw the rejection.

III. Nonstatutory Double Patenting Rejection

The Examiner has rejected claims 1-13 on the grounds of a non-statutory obviousness-type double patenting in view of United States Patent Number 6,669,929 for "Dentifrice Containing Functional Film Flakes," also owned by Colgate-Palmolive Company.

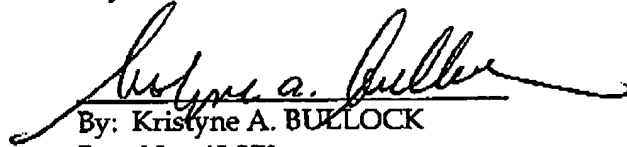
The applicants have enclosed with this Response and Amendment a Terminal Disclaimer and Statement of Common Ownership." In view of this submission, the Examiner's rejection is no longer applicable. Its reconsideration and withdrawal are respectfully requested.

CONCLUSION

For the reasons discussed above, it is respectfully submitted that the claims are distinguishable over the prior art. The reconsideration and withdrawal of each of the rejections and allowance of the claims at the earliest opportunity are respectfully requested.

Respectfully submitted,

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